

The three claims against Biovail and GSK are (1) a violation of section 2 of the Sherman Act, which prohibits monopolization; (2) a separate violation of section 2 of the Sherman Act on the basis of conspiring to monopolize; and (3) a violation of section 1 of the Sherman Act, which prohibits contracts or combinations in restraint of trade.

Biovail and GSK submitted separate motions to dismiss the complaint. Biovail argues that the complaint does not allege that either party formed a monopoly, which is fatal to the first Section 2 claim. Biovail also argues that the complaint does not sufficiently allege concerted action sufficient to state a claim for conspiracy under either section 1 or 2. GSK argues that the complaint alleges no actions on its part that caused any of the alleged harms and also that the complaint insufficiently states a claim for conspiracy or concerted action.

I. Legal Background

Certain provisions of federal law relating to the procedures for approving new drugs are at the center of the plaintiffs' allegations. The plaintiffs claim that Biovail and GSK abused provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-392 ("FDCA"), for the purpose of delaying the marketing of generic versions of their drug Wellbutrin XL.

The FDCA provides two different sets of procedures for the approval of new drugs. First, the manufacturer of a new drug must obtain approval from the Food and Drug Administration ("FDA") by filing a New Drug Application ("NDA"). This application contains data as to safety and effectiveness. In filing an NDA, manufacturers also list any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the drug prior to the expiration of the listed patents. These patents are listed in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations (known as the "Orange Book"). The complaint states that the FDA does not exercise tight supervision over the contents of the Orange Book, relying on manufacturers to list patents in good faith. Compl., ¶ 33.

The second approval procedure was established in 1984 by the Hatch-Waxman Amendments. Pub. L. No. 98-417, 98 Stat. 1585 (1984). The purpose of the Amendments was to speed the approval of generic versions of brand-name drugs while respecting brand manufacturers' patent rights. Generic manufacturers need not file NDAs. Instead, they may file Amended New Drug Applications ("ANDAs"). ANDAs require a showing of safety and effectiveness and a showing of bioequivalency to an approved brand-name drug. Bioequivalency refers to equivalency of the active ingredient,

dosage, route of administration and strength between a brand-name and generic drug. Compl., ¶ 10.

As part of an ANDA, generic manufacturers must certify that they will not infringe any brand manufacturers' patents. One method of certification is referred to as a "Paragraph 4" certification, which requires the generic manufacturer to state that a potentially conflicting Orange Book patent is either invalid or will not be infringed by the proposed generic.

The Hatch-Waxman Amendments seek to protect brand manufacturers' patents. In the case of an ANDA including a Paragraph 4 certification, brand manufacturers have 45 days from the date of notice of the ANDA's filing to initiate litigation on any potentially infringed patents. If the brand manufacturer brings suit within that 45 day window, then the FDA may not give final approval to the generic drug for the shorter of 30 months or a finding by the court that the patent is invalid or not infringed.

The plaintiffs also base their complaint on a separate provision of the FDCA. Section 505(j) of the FDCA allows for a person (including a corporation) to file a "Citizen Petition" requesting that the agency take or refrain from taking any administrative action, which may include the approval of a generic drug. The FDA must respond to these petitions within 180 days of their filing. The plaintiffs allege that, until a 2007

amendment to the FDCA, it was common practice for the FDA to withhold ANDA approval until after consideration of a Citizen Petition. Compl., ¶ 43.

II. Allegations of the Plaintiffs' Complaint

The plaintiffs allege that GSK and Biovail have acted in concert to abuse the provisions of the Hatch-Waxman Amendments by filing meritless litigation in an effort to delay the entry of generic competitors into the American market for Wellbutrin XL. They also allege that Biovail filed a baseless citizen petition with the FDA in a further attempt to delay the generics' market entry.

The complaint makes the following assertions. Biovail and Pharma Pass, LLC, collaborated to create an extended release formula for bupropion hydrochloride in the 1990s. Compl., ¶ 66. Pharma Pass's chemists created an extended release version of the drug using off-the-shelf chemical compounds unworthy of patent protection in themselves. However, they were able to acquire a patent on their formula by claiming that it was "free of stabilizer of any kind." "Stabilizer" is the term used for a chemical or compound that prolongs the release of a drug after initial administration. This formula received patent No. 6,096,341 (the "341 patent"). Id., ¶¶ 70-71. A continuation of the 341 patent was issued on November 7, 2000. This patent

number was 6,143,327 (the "327 patent"). Id., ¶ 86. Biovail acquired Pharma Pass in December of 2002 and later obtained the rights conferred by the 341 and 327 patents. Id., ¶ 87.

On October 26, 2001, Biovail and GSK entered into a contract to promote and distribute Wellbutrin XL in the United States and Canada. Id., ¶ 89. In August of 2002, GSK filed a New Drug Application ("NDA") with the FDA. GSK listed the 341 and 327 patents in the FDA's Orange Book as patents that could reasonably be asserted to cover Wellbutrin XL. Id., ¶ 91. The plaintiffs assert that the 327 patent was improperly listed in the Orange Book because it did not conform to the description of the underlying 341 patent. Id., ¶¶ 137-38. The FDA issued approval of Wellbutrin XL to GSK on August 8, 2003. Id., ¶ 92. On December 31, 2004, the 341 and 327 patents were formally assigned to Biovail. Id., ¶ 95.

On September 21, 2004, Anchen (a generic manufacturer of bupropion hydrochloride) filed an ANDA seeking FDA approval to market Wellbutrin XL's generic alternative in a 150mg and 300mg formulation. Anchen's ANDA included a Paragraph 4 certification that stated that it would not infringe the 341 or 327 patents. The basis for this assertion was the presence of "stabilizer" compounds in the Anchen generic version. Id., ¶ 101. On September 23, 2004, Abrika, another generic manufacturer, filed a similar ANDA, as did the manufacturer Impax on November 30, 2004.

Id., ¶¶ 105, 108. On July 21, 2005, the manufacturer Watson filed a similar ANDA for the 300mg formulation of bupropion hydrochloride. Id., ¶ 111.

The complaint alleges that on December 21, 2004, GSK and Biovail filed an action against Anchen alleging infringement of the 341 and 327 patents in the Central District of California. The same claims were made by GSK and Biovail against Abrika in the Southern District of Florida. Id., ¶ 114-15. In both cases, the claims based on the 327 patent were eventually withdrawn. Id., ¶ 142. On March 7, 2005, Biovail filed an action against Impax alleging a violation of the 341 patent. Id., ¶ 116. Biovail later filed suit against generic manufacturer Watson. Id., ¶ 132.

The plaintiffs allege that all of the generic competitors provided the defendants with access to their ANDAs and sample products to allow them to compare the products to Wellbutrin XL and its applicable patents. Id., ¶ 119. They allege that these proffers demonstrated conclusively that the generic formulations did not infringe Wellbutrin XL's patents because of the presence of stabilizer in the generics. Compl., ¶ 124.

The plaintiffs allege that GSK co-filed the Anchen and Abrika suits with Biovail. The complaint states that "in response to Abrika's motion to dismiss GSK, GSK stated that it

should be permitted to remain in the action because '[a]n injunction is as important to SmithKline as it is to Biovail.'" Id., ¶ 132. GSK eventually moved to withdraw from the suits filed against Abrika and Anchen. GSK "represented to the Court that it would be 'bound by the decision in the [Abrika] action,' not sue with respect to the patents and the ANDA products at issue in the action, and provide discovery 'as if it were a party to this action.'" Id., ¶ 133.

GSK was not a party to the Impax litigation, but was listed in the complaint as the owner of the NDA, the licensee of the 341 patent and the party responsible for listing the 341 patent in the Orange Book. Id., ¶ 134. Moreover, the complaint alleges that GSK remained a real party in interest in the infringement actions and continued to act in concert with respect to matters involving that litigation and the sham petitioning. Id., ¶ 135.

Anchen received FDA tentative approval for its generic version of Wellbutrin XL on November 14, 2005, but was unable to manufacture and market its product because of the ongoing patent infringement litigation. A generic version of Wellbutrin XL, therefore, was allegedly ready for market entry on November 14, 2005. Id., ¶ 143.

On December 20, 2005, Biovail filed a citizen petition with the FDA allegedly for the sole purpose of blocking the

generics' entry to market. Id., ¶ 145. The plaintiffs claim that the FDA had a practice of delaying approval of generic drugs until the resolution of a citizen petition. Id., ¶ 157. On December 14, 2006, the FDA denied Biovail's citizen petition and, on the same day, granted final approval to Anchen's and Abrika's ANDAs. Id., ¶ 155.

On December 15, 2006, the FDA gave Impax tentative approval for its 150 mg formula and final approval of its 300 mg formula. On June 13, 2007, the FDA gave Watson final approval for its 300 mg formula. Id., ¶156. Biovail settled its litigation with Anchen and Impax before either had gone to summary judgment. The plaintiffs claim this highlights the sham nature of the suits. Id., ¶ 160-61. These settlements barred generic competitors from releasing their 150 mg formulas until 2008. Id., ¶ 163.

III. Analysis

The United States Court of Appeal for the Third Circuit has summarized the holding of Bell Atlantic Corporation v. Twombly, 127 S. Ct. 1955 (2007), which states the applicable pleading standard in the face of a motion to dismiss:

The Supreme Court's Twombly formulation of the pleading standard can be summed up thus: "stating ... a claim requires a complaint with enough factual matter (taken as true) to suggest" the required element. This "does

not impose a probability requirement at the pleading stage," but instead "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of" the necessary element.

Phillips v. County of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008).

The Court finds that the plaintiffs have alleged sufficient facts to suggest that discovery will reveal evidence of each element of their claims, with the exception of their claim of substantive monopolization against Biovail.

A. Conspiracy to Monopolize Under Section 2 of the Sherman Act

Although the complaint's first count is based on a theory of substantive monopolization, the facts at the heart of this case relate to a conspiracy between Biovail and GSK to monopolize the bupropion hydrochloride market in the United States through a series of actions designed to impede the marketing of their generic competitors. The Court will address the two counts requiring an allegation of conspiracy or concerted action before turning to the substantive monopolization claim, which relies in part on the sufficiency of the conspiracy allegations.

The parties agree that the elements of a charge of conspiracy to monopolize under section 2 of the Sherman Act are (1) an agreement between two or more economic entities; (2) a

specific intent to monopolize the relevant market; (3) the commission of an overt act in furtherance of the alleged conspiracy; and (4) that there was a dangerous probability of success.

Both GSK and Biovail argue that the complaint fails to sufficiently allege concerted action or a conscious commitment to a common scheme designed to achieve an anticompetitive objective. In the context of a section 1 concerted action claim, the Supreme Court held "that stating such a claim requires a complaint with enough factual matter (taken as true) to suggest that an agreement was made. Asking for plausible grounds to infer an agreement does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal agreement." Twombly, at 1965.

The Court also held that "when allegations of parallel conduct are set out in order to make a § 1 claim, they must be placed in a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action." Id. at 1966. These statements have been held by other courts to apply to concerted action alleged under section 2. Behrend v. Comcast Corp., 532 F.Supp.2d 735 (E.D. Pa. 2007); In re Elevator Antitrust Litigation, 502 F.3d 47 (2d Cir. 2007).

Although the Court recognizes that the facts alleged in this complaint present a close question of adequacy, the plaintiffs have sufficiently alleged a section 2 conspiracy claim. The allegation of a joint filing of sham litigation is enough to state the elements of (1) agreement, (2) intent to monopolize, (3) an overt act, and (4) dangerous probability of success.

GSK argues that the facts alleged are as consistent with unilateral action as with an illegal conspiracy, and therefore do not meet the Twombly standard of pleading. However, unlike in Twombly, the plaintiffs have not simply alleged a series of parallel actions by competitors, but have alleged joint action by GSK and Biovail in the form of the first two infringement suits and a coordinated use of FDA regulations in order to delay generic competitors. The allegations do not relate to two competing enterprises who engaged in apparently coordinated business tactics. In this case, the allegation is that GSK and Biovail performed a single, joint action in order to frustrate the marketing of generic competitors.

The filing of the Anchen and Abrika litigation is the factual allegation that allows the plaintiffs' case to progress. GSK has argued (1) it was not involved in those suits but was joined by Biovail pursuant to a contract granting Biovail the right to control all patent litigation affecting Wellbutrin XL,

Oral Arg. Tr. at 24; and (2) that GSK's withdrawal, along with the withdrawal of the claims under the 327 patent, means that GSK cannot be causally linked to any injury to the plaintiffs. GSK Mot. at 10-14.

GSK has cited to the record of both the Anchen and Abrika cases in order to establish that Biovail was completely in control of listing GSK as a plaintiff in those suits. First, they note that GSK's motions to withdraw in both cases state that Biovail filed the complaints in GSK's name pursuant to a "contractual right to fully control all aspects of [the] litigation and, in that light, has joined plaintiff [GSK] to this case." Oral Arg. Tr. at 24. GSK provided these motions to withdraw to the Court at oral argument. Biovail Lab., Inc., et al. v. Anchen Pharm., Inc., No. 04-01468 (C.D. Cal. April, 21, 2005) ("Anchen Withdrawal Motion"); Biovail Lab., Inc., et al. v. Abrika, LLP, et al., No. 04-61704 (S.D. Fla. April 18, 2005) ("Abrika Withdrawal Motion"). GSK also notes that the lawyers listed as representing GSK differ from the complaints in those cases to the motions for withdrawal. They state that this suggests that the lawyers who initially filed the complaint were working for Biovail, not GSK.

GSK's corporate name appears on both the original and amended complaints in the Abrika suit. Moreover, the plaintiffs have asserted that GSK only withdrew from those two cases after

Anchen and Abrika filed motions to dismiss GSK as a plaintiff for lack of standing. The plaintiffs allege that GSK actually fought to stay in those suits. Compl., ¶ 132-33. In examining the record of those two cases, the Court learned that in the suit against Abrika, the defendant (Abrika) twice moved to dismiss GSK on the basis of a lack of standing. Abrika, No. 04-61704 (S.D. Fla. Jan. 18, 2005); Id., No. 04-61704 (S.D. Fla. Mar. 1, 2005). Furthermore, the lawyer who eventually signed GSK's motion to withdraw also had his name included on a motion to disqualify the defendant's counsel based on a purported conflict of interest. Id., No. 04-61704 (S.D. Fla. Mar. 23, 2005) (listing Jason A. Lief of Morgan, Lewis & Bockius, LLP, as of counsel for the plaintiff).

The Court cannot say on the basis of this record that the plaintiffs' allegation that GSK participated in the allegedly baseless patent infringement suits is unfounded. The Court finds that, taken together with GSK's listing of Biovail's patents in the Orange Book and the two companies' history of cooperation with respect to the development and marketing of Wellbutrin XL, the plaintiffs' claim that GSK and Biovail acted together in filing at least these two infringement suits states the necessary element of agreement and concerted action. Therefore, the claim for conspiracy under section 2 of the Sherman Act may progress against both Biovail and GSK.

B. Concerted Action in Restraint of Trade under Section One of the Sherman Act

____ “[T]o succeed on a § 1 claim, a plaintiff must meet two requirements. First, the plaintiff must show that the defendant was a party to a ‘contract, combination . . . or conspiracy.’” Second, the plaintiff must show that the conspiracy to which the defendant was a party imposed an unreasonable restraint on trade.” Toledo Mack Sales & Serv., Inc. v. Mack Trucks, Inc., 530 F.3d 204, 218 (3d Cir. 2008). The complaint states that the defendants would be liable under either a per se or a “rule of reason” analysis. Compl., ¶¶ 214-15. A “rule of reason” analysis would require specific proof of an unreasonable restraint of trade. Under such an analysis, the plaintiff would need to establish the relevant product and geographic markets, as well as the defendants’ market power. The plaintiffs do allege a product market, a geographic market and that the defendants possessed power over those markets. The defendants do not challenge the plaintiffs’ allegations regarding markets or market power; only the conspiracy element is challenged.

The arguments and conclusions outlined above with respect to the conspiracy claim under section 2 apply equally to this count. As under section 2, the plaintiffs state a valid claim of concerted action under section 1 of the Sherman Act on the basis of their allegations of improper joint litigation.

C. Substantive Monopolization Under Section 2 of the Sherman Act

The parties agree that the elements to be alleged for a section 2 monopolization claim are (1) the possession of monopoly power and (2) the willful acquisition and maintenance of that power as distinguished from growth or development or consequences of a superior product, business acumen, or historical accident. Crossroads Corp. v. Orange & Utilities, Inc., 159 F.3d 129, 141 (3d Cir. 1998). The complaint states that the relevant geographic market is the United States and its territories; the relevant product market is Wellbutrin XL and its generic equivalents. GSK and Biovail have separate arguments as to the insufficiency of the plaintiffs' complaint on this count.

1. Biovail

Biovail argues that the complaint fails to plead that it possessed a monopoly in any relevant market. Biovail is correct that the plaintiffs do not state that Biovail possessed a monopoly in the relevant product market. Instead, the complaint states that the "defendants" possessed monopoly power over Wellbutrin XL and its equivalents. Compl., ¶¶ 168-178.

The plaintiffs have argued that their allegations of monopoly extend to a "joint venture" or "joint dealing" between Biovail and GSK. Opp'n at 41; Oral Arg. Tr. at 91. The plaintiffs argue that they may allege that a single "economic

entity" possessed the monopoly, and that their allegations sufficiently state that Biovail and GSK acted as a single economic entity. Opp'n at 41.

The plaintiffs' briefs are unclear on the exact nature of their argument. They use the term "joint venture" to describe the relationship between Biovail and GSK, but they never plead or argue that the two met the definition of a joint venture under any applicable business enterprise law. Instead, they use the term in a less formal sense, meaning a close relationship designed to bring a single product to market. Opp'n at 42-46.

The plaintiffs cite to a case that would seem to undermine their position. Sun Dun of Washington v. The Coca Cola Co., 740 F. Supp. 381, 391 (D. Md. 1990). Sun Dun states that "[t]he idea that a monopoly is composed of a single economic entity is also reflected in the requirement in an actual monopolization claim that the requisite market power be held by a single defendant." Id. (emphasis added). Nowhere in the complaint is Biovail identified as the single defendant possessing market power.

The plaintiffs also cite a case from the United States Supreme Court, Texaco Inc. v. Dagher, 541 U.S. 1 (2006), to support their claim that joint ventures can be treated as single economic entities. Texaco, however, concerned an actual joint venture, i.e., a single corporate entity created by two other

corporate entities who stood as its primary investors. Biovail makes no allegation that such an entity exists in this case.

Biovail does not sell Wellbutrin XL in the United States. The plaintiffs recognize that Biovail does not directly distribute Wellbutrin XL in the U.S. market. Opp'n at 23. Discussing their second count, the plaintiffs state that "GSK was able to maintain 100% control of the U.S. market for extended release bupropion." Id. at 39. The plaintiffs' brief in opposition states that "Biovail competes in the relevant market through its agreements and joint venture with GSK." Id. at 46. Its argument in support of this statement is a rehashing of the arguments related to the "single economic entity" theory. Again, not only are there insufficient facts to establish that Biovail and GSK have formally established a joint venture, but the pleadings themselves assert that GSK is a licensee of Biovail rather than a joint venturer.

The gist of this complaint is that GSK had a monopoly on the distribution and sale of extended release bupropion in the United States and that Biovail conspired to help GSK maintain that monopoly. Biovail profited as a recipient of royalties on GSK's profits from sales of Wellbutrin, but did not participate in the U.S. market directly. The complaint fails to state a claim of substantive monopolization against Biovail under section

2 of the Sherman Act, and therefore the claim will be dismissed as to Biovail.

2. GSK

With respect to the substantive monopolization claim under section 2 of the Sherman Act, GSK argues that the plaintiffs have not alleged any action taken by GSK that could have caused harm to the plaintiffs. First, GSK states that all of its actions with respect to listing patents in the Orange Book were proper and actually required by law. Second, GSK argues that it played no active role in the suits against Anchen or Abrika, and that it withdrew from those suits prior to any decisions on the merits. GSK asserts that even if the filing of patent 327 in the Orange Book was improper, it was not the proximate cause of harm to the plaintiffs because the Hatch-Waxman Act's freeze on the generic drugs' approval would have applied regardless due to the inclusion of the 341 patent as a basis for filing the Anchen and Abrika suits. Finally, GSK argues that the complaint does not allege that GSK played any role in the subsequent Impax and Watson infringement suits or the filing of the citizen petition with the FDA.

On the basis of the pleadings and documents before it, the Court cannot say at this stage that GSK's alleged actions caused no injury to the plaintiffs. The Abrika and Anchen suits were filed in December of 2004. The filing of these suits began

a 30 month freeze on the generic drugs' ability to market their products in the absence of a positive court ruling or the withdrawal of that litigation prior to the 30 month limit. The Court cannot say at this point that GSK's withdrawal from that litigation constituted a withdrawal from the alleged conspiracy, which continued to cause injury to the plaintiffs. GSK's alleged co-conspirator continued those suits well past the 30 month statutory freeze. Indeed, GSK acknowledges that in the absence of the infringement actions, the first generic manufacturers could have entered the market as of November of 2005, when the FDA granted tentative approval of the drugs. Oral Arg. Tr. at 18:12-15.

GSK's argument hinges on a finding that the plaintiffs have failed to state a claim for conspiracy or concerted action. GSK attempts to separate the substantive monopolization claim from the conspiracy claim, but the same actions state a claim for both claims. While it may be true that "separating the conduct [of] GSK from Biovail . . . there's nothing in the complaint that directly caused or proximately caused any injury to the plaintiffs," Oral Arg. Tr. at 10, the complaint does not separate those actions, nor does the record clearly contradict the plaintiffs' allegations. See supra Part III.A.

Based on all of the allegations of the complaint, the Court finds that the plaintiffs have sufficiently pleaded a claim

for monopolization against GSK. As discussed above, the Court finds that the plaintiffs have adequately alleged a conspiracy between GSK and Biovail to maintain GSK's monopoly over the American market for Wellbutrin XL. Those allegations apply equally to the substantive claim of monopoly against GSK, which stands as the actual monopolist under the plaintiffs' theory of the case. Unlike Biovail, GSK was a participant in the relevant market whose position as licensee of Biovail's patents ensured them a monopoly on sales of Wellbutrin XL in the United States.

IV. Conclusion

The Court will deny the defendants' motions to dismiss with respect to the plaintiffs' claims of conspiracy to monopolize (count two) and concerted action in restraint of trade (count three). The Court will also deny GSK's motion to dismiss the plaintiffs' substantive monopolization claim under section 2 of the Sherman Act. The Court will grant Biovail's motion to dismiss the substantive monopolization claim under section 2 of the Sherman Act.

An appropriate order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: WELLBUTRIN XL	:	CIVIL ACTION
ANTITRUST LITIGATION	:	
	:	
	:	
	:	NO. 08-2431 (direct)

ORDER

AND NOW, this 13th day of March, 2009, upon consideration of the defendants' motions to dismiss the direct purchaser plaintiffs' complaint (Docket Nos. 48 and 49), the plaintiffs' consolidated opposition and the defendants' replies thereto, and following oral argument on the motions held on February 26, 2009, IT IS HEREBY ORDERED that the defendants' motions are GRANTED in part and DENIED in part. The Biovail defendants' motion is GRANTED with respect to the plaintiffs' claim of substantive monopolization under section 2 of the Sherman Act; the motions are otherwise DENIED.

BY THE COURT:

/s/Mary A. McLaughlin
MARY A. McLAUGHLIN, J.